such an increase is desirable, comprising:

(a) identifying a subject in which an increase in muscle mass or function is desirable; and

(b) administering to the subject a safe and effective amount of a compound that selectively acts through the VPAC receptor.

In the Specification

Please amend page 9, lines 7 – 11 of the specification as follows:

Legend for the X-axis: 1: Saline + Dexamethasone (1.2 mg/kg/day included in the drinking water), 2 PACAP-38 (0.1mg/kg) + Dexamethasone +T, 3: PACAP-38 (0.3 mg/kg) + Desamethasone + T, 4: $VPAC_1R$ agonist (0.1 mg/kg) + Dexamethasone + T, 5: $VPAC_1R$ agonist (0.3 mg/kg) + Dexamethasone + T, 6: $VPAC_2R$ agonist (0.1 mg/kg) + Dexamethasone + T, 7: $VPAC_2R$ agonist (0.3 mg/kg) + Dexamethasone + T.

REMARKS

Invention Synopsis

The present invention relates to the use of VPAC receptors to identify canidate compounds that are potentially useful in the treatment of skeletal muscle atrophy and/or useful to induce skeletal muscle hypertrophy.

Amendment

The above amendments simply claim the meets and bounds of the present invention. Support for amendments to Claims 16 and 27 can be found throughout the specification, specifically page 12, lines 7. The amendment to the specification matches the legend description to the drawing. No new matter is involved with the amendments to the claims. Applicants respectfully request the amendments be entered and all the claims of the present invention be allowed.

Restriction Requirement

The Examiner finally rejected Applicants traversal of the restriction requirements. Therefore, Claims 15, 16 (in part), 17 and 27 are pending. Cancellation of claims requires no amendment to Inventorship.

35 U.S.C.§112, first paragraph Rejection

Claims 15-17 and 17 stand rejected under 35 U.S.C.§112, first paragraph, as containing subject matter not described in the specification is such a way as to enable one skilled in the art

to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Claims of the instant case are directed to a method of identifying compounds and the use of these compounds. Applicants have provided specific examples within the application of compounds that fall within the Markush group claimed. The Examiner maintains that it would require a large quantity of experimentation for the other compounds claimed. Applicants respectfully disagree.

While the compounds cited in the present invention may act upon other receptors, the invention of the present application is that compounds are selective for the VPAC receptor. As stated within the specification "selective agonist means that the agonist has significantly greater activity toward a certain receptor(s), not that it is completely inactive with regard to other receptors." Screening methods as described in the specification can be easily used to identify these compounds. There may be some experimentation required but the experimentation would not be considered unduly.

35 U.S.C.§112, second paragraph Rejection

Claims 15-17 and 27 stand rejected under 35 U.S.C.§112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically the Examiner points to the phrase "safe and effective." The Examiner states that this phrase is unclear. Applicants respectfully disagree.

Applicants have discussed what is meant by safe and therapeutically effective compounds on page 35 line 22 through page 36 line 2 of the specification. Once a compound is identified as useful in the treatment of a condition, standard tests can be run to ascertain its efficacy and safety. This is common practice in the pharmaceutical industry.

35 U.S.C.§102(b)

Claim 15 stands rejected under 35 U.S.C.§102(b) as being anticipated by Gourlet et al., WO 98/02453). The Examiner maintains that Gourlet et al. teach peptides that are highly selective for the VIP1 (=$VPAC_1$) receptor, are agonists or antagonists, and pharmaceutical compositions comprising the peptides and a pharmaceutically acceptable carrier. Applicants traverse the rejection in that Gourlet et al do not disclose pharmaceutical compositions for the treatment of muscle conditions.

Claims 16, 17 and 27 stand rejected under 35 U.S.C.§102(b) as being anticipated by Vittone et al., Metabolism, vol 46, pp. 89-96, 1997). The Examiner avers that Vittone et al. teach improved muscle function in elderly men after administration of single nightly injections of

GHRH. Applicants respectfully disagree that Vittone either teaches or suggest the present invention. The muscle results of Vittone et al are not obtained by the interaction of a selective agonist with the VPAC receptor. The muscle effects are being obtained via another mechanism. The doses administered by Vittone et al are probably not hitting the VIP1 receptor and definitely not hitting the VIP2 receptor. Therefore, Vittone et al neither teaches or suggests the role of VPAC receptors in muscle conditions.

CONCLUSION

Attached hereto is a marked-up version of the changes made to the claims by the current amendment, wherein text which has been added is underlined and text which has been deleted is bracketed. The attached page is captioned **"Version with markings to show changes made."**

In light of the amendments to the claims and the above remarks, it is requested that the Examiner reconsider and withdraw the rejections under 35 U.S.C.§112 first and second paragraphs and 35 U.S.C.§102(b).

Respectfully submitted,
R. J. Isfort et al.

By M P McMahon
Mary Pat McMahon
Attorney for Applicants
Registration No. 34,673
(513) 622-5502

May 30, 2002
Cincinnati, Ohio
8311firstofficeresponse.doc

VERSION WITH MARKINGS TO SHOW CHANGES MADE

15. (Amended) A pharmaceutical composition for the treatment of muscle diseases, comprising:

(a) a safe and effective amount of a VPAC receptor agonist; and

(b) a pharmaecutially-accepatable carrier.

16. (Twice Amended) The method for increasing skeletal muscle mass or function according to Claim 27 in a subject wherein the compound is a selective VPAC receptor agonist. [in which such an increase is desirable, comprising:

[(a) identifying a subject in which an increase in muscle mass or function is desirable; and

[(b)] (a) administering to the subject a safe and effective amount of said compound selected from the group consisting of a VPAC receptor agonist, a compound that prolongs or augments the activation of VPAC receptors or the activation of a VPAC receptor signal transduction pathway, an expression vector encoding a functional VPAC receptor, an expression vector encoding a constitutively active VPAC receptor, a compound that increases expression of VPAC receptors, a compound that increases expression of VIP and a compound that increases expression of a VIP analog.]

27. (Amended) A method for increasing skeletal muscle mass or function in a subject in which such an increase is desirable, comprising:

(c) identifying a subject in which an increase in muscle mass or function is desirable; and

(d) administering to the subject a safe and effective amount of a compound that selectively acts through the VPAC receptor.